

REMARKS

This response is submitted in response to the non-final Office Action mailed on February 9, 2005. Claims 1-19 are pending in this application. In the Office Action, Claims 1-2, 4-6 and 17 are rejected under 35 U.S.C. §102 and Claims 1-8 are rejected under 35 U.S.C. §103. In view of the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-2, 4-6 and 17 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,407,957 to Kyle et al. ("*Kyle*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Independent Claim 1 recites, in part, a stable oil containing one or more long-chain polyunsaturated fatty acids obtainable from a biomass, in the form of triacylglycerols serving both as transfer medium for the long-chain polyunsaturated fatty acids from the biomass and as carrier for the long-chain polyunsaturated fatty acids in food, nutritional, pharmaceutical or cosmetic products and into which the long-chain polyunsaturated fatty acids are incorporated such that at least 60% by weight of the long-chain polyunsaturated fatty acids present in the biomass are present in the oil but that less than 10% of phosphorus that is present in the biomass is present in the oil, so that the oil does not require purification prior to use.

The present claims relate to an improved process and product, more specifically to an improvement in the final stage of a process for recovering long chain polyunsaturated fatty acids (LC-PUFA) such as, for example, arachidonic acid (ARA) and docosahexaenoic acid (DHA) from organisms producing the same. In the conventional process, the organism is cultivated in a fermentor, the biomass is harvested and the LC-PUFA is recovered from the biomass. The recovery step conventionally consists of solvent extraction using hexane. See, *Kyle*, column 5, line 47 to column 6, line 2.

Nevertheless, this process suffers from a number of disadvantages. See, specification, page 1, lines 30-39. For example, during the stages of extraction with hot solvent or of distillation of the solvent, the LC-PUFAs may undergo degradation in contact with oxygen. The complete removal of the solvent contained in the oil or in the residual biomass requires a heat treatment at high temperature. Moreover, the solvent, such as hexane, is capable of dissolving nontriacylglycerol constituents of the biomass which in fact constitute impurities. The crude oil

obtained after evaporation of the solvent should further undergo several refining stages comprising degumming, neutralization with alkali, decolorization, dewaxing and deodorization with the aim of at least partially removing the impurities. This means that the highly unsaturated oil is exposed to conditions stimulating physicochemical reactions which affect its quality. For example, the decolorization agents create a system of conjugated double bonds and form degradation products by chemical reaction with the oxidized glycerides.

In contrast, the novelty of the present claims resides in the realization that it is possible to recover the LC-PUFA from the biomass simply by harvesting it, drying it, mixing it with an edible oil into which the LC-PUFA dissolves and extracting the edible oil that now contains most of the LC-PUFA from the biomass by pressing and filtration. After deodorizing, the oil can be used directly as the lipid content of a food stuff such as, for example, infant formula.

Further, the present claims seek to avoid the disadvantages of the prior art, by providing a stable oil containing one or more polyunsaturated fatty acids derived from biomass in the form of triacylglycerols in the purified state and which has undergone minimum degradation. See, specification, page 2, lines 12-17.

Claim 1 is directed, in part, to cover the use of an edible oil as both the medium used to recover the LC-PUFA from the biomass and an ingredient in foodstuffs. In contrast, *Kyle* fails to disclose or suggest using the oil recovered from the biomass as a food ingredient because *Kyle* clearly envisions the necessity for an extraction step using an inedible solvent such as hexane, which teaches away from the present claims. See, *Kyle*, column 5, line 47 to column 6, line 2. Further, the oil recovered from the biomass would not be suitable for direct use as a food ingredient because it contains too much DHA and is described as "crude" with a "yellow orange color." See, *Kyle*, column 5, lines 55-60. Essentially, *Kyle* teaches oil recovered from biomass that is a crude DHA rich oil which needs further refining to produce a purified DHA-rich oil capable for addition to products such as infant formula. For the reasons discussed above, Applicants respectfully submit that Claim 1 and Claims 2, 4-6 and 17 that depend from Claim 1 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicants respectfully request that the rejection of Claims 1-2, 4-6 and 17 under 35 U.S.C. §102(b) be withdrawn.

In the Office Action, Claims 1-18 are rejected under 35 U.S.C. §103 as being unpatentable over *Kyle* in view of EP 0322227 to Akimoto et al. ("*Akimoto*") further in view of U.S. Patent No. 5,871,757 to Cloughley et al ("*Cloughley*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

As discussed previously, *Kyle* is deficient with respect to Claim 1 because *Kyle* discloses oil recovered from biomass that is a crude DHA rich oil which needs further refining to produce a purified DHA-rich oil capable for addition to products such as infant formula, which teaches away from the present claims. Similarly, *Kyle* fails to disclose or suggest Claim 7 because Claim 7 is directed to, in part, a process for preparing a stable oil which comprises bringing a carrier oil into contact with a biomass obtained from the culture of a microorganism containing one or more long-chain polyunsaturated fatty acids, so as to transfer the long-chain polyunsaturated fatty acid(s) in the form of triacylglycerols to the carrier and form a biomass residue, separating the oil containing the fatty acid(s) from the biomass residue, and then deodorizing the separated oil to obtain the stable oil without purification.

Moreover, *Akimoto* and *Cloughley* fail to remedy the deficiencies of *Kyle* with respect to the present claims. For example, *Akimoto* describes the production of bishomo- γ -linoleic acid by cultivation of a microorganism that is also capable of producing ARA. *Akimoto* proposes to add oils such as sesame or peanut oil to the fermentation medium to suppress the production of ARA and increase the production of bishomo- γ -linoleic acid. See, *Akimoto*, column 1, lines 21-26. *Cloughley* relates to a technique to stabilize any polyunsaturated oil against oxidation by adding an essential oil. See, *Cloughley*, column 2, lines 16-21. Nevertheless, *Akimoto* and *Cloughley* along with *Kyle* fail to disclose an edible oil, or process for making same, as both the medium used to recover the LC-PUFA from the biomass and an ingredient in foodstuffs without purification as required, in part, by the present claims. Further, the Patent Office has not even explained what features of *Akimoto* and *Cloughley* could be used to modify the process disclosed in *Kyle* to arrive at the present claims. Thus, even the combination of the cited references fails to disclose or suggest all of the claimed elements.

For the reasons discussed above, the combination of *Kyle* in view of *Akimoto* and *Cloughley* does not teach, suggest, or even disclose the present claims, and thus, fails to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1-18 be reconsidered and the rejections be withdrawn.

Applicants note for the record that Claim 19 has not been rejected. Thus, Applicants request that the record reflect that this claim be allowed as presently pending or objected to as being dependent upon a rejected base claim. To the extent that the Patent Office had intended to reject these claims as well, Applicants believe that the subject matter as defined therein is patentable at least for substantially the same reasons as discussed above.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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